

# EXHIBIT 1

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

NOVARTIS PHARMA AG,

Plaintiff,

v.

INCYTE CORPORATION,

Defendant.

**Case No. 1:20-cv-00400-GHW-GWG**

**Judge Gregory H. Woods**

**Magistrate Judge Gabriel W. Gorenstein**

**LINDA M. PULLAN, Ph.D. EXPERT REPORT**

The following report is provided pursuant to Federal Rule of Civil Procedure 26(a)(2). My opinions are based on my education, training, knowledge, experience, and/or materials I have considered in connection with this litigation, which are listed on **Exhibit A**. I reserve the right to supplement that list and my opinions set forth in this report. I also reserve the right to respond to and rebut all information provided in discovery and any opinions offered by Defendant's experts.

**QUALIFICATIONS AND BACKGROUND**

I have approximately 40 years' experience in the pharmaceutical industry, with about 28 years in business development and licensing and pursuing and negotiating licensing transactions on behalf of pharmaceutical companies. My CV, which includes this experience, is attached to this report as **Exhibit B**.

I received my B.S. in chemistry from the University of Utah and my Ph.D. in biochemistry from the University of California, Riverside. After I received my Ph.D., I spent 10 years in drug discovery research, first with Monsanto Healthcare which became Searle (and is now part of Pfizer), and then with Imperial Chemical Industries which became Zeneca Pharmaceuticals (and now AstraZeneca). During this time, I worked on multiple drug discovery and early development projects. I was team leader for what became Seroquel, a well-known drug to treat schizophrenia, with billions in sales at its peak. In 1994, I switched from drug discovery to licensing, with a role in identifying deal opportunities, evaluating them, and negotiating licensing deals.

My experience in licensing continued at Amgen where I was director of oncology and hematology licensing for about eight years. Ultimately, I led a 10-member team (which included finance and legal representatives assigned to oncology licensing) focused on transactions ranging from collaborating on technologies to company acquisitions. I left Amgen to join Kosan Biosciences, where I was VP of Business Development until the company was sold. At that time, I began consulting, and for about 16 years have effectively continued the same business

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development and licensing role at Pullan Consulting. Currently, Pullan Consulting includes myself and two other business development and licensing professionals, plus support staff.

In my role as founder and owner of Pullan Consulting, I have worked on approximately 100 signed deals (not counting those done before consulting) and many more term sheets as advisor or negotiator. These deals have ranged from university licenses to Phase III drug licenses to a company acquisition. In 2021 alone, for example, my clients have included venture-backed companies and publicly-traded companies, U.S. companies and foreign companies (European, Asian, and Latin American), companies seeking to out-license and companies seeking to in-license, some universities who want help doing out-licensing deals, a couple of consulting firms (for our deal expertise), and sometimes venture firms (for our assessments of opportunities). Among the clients active in 2021 and 2022 were 1200 Pharma, Abintus, Aeon Respire, Aeromics, Alacrita Consulting, AliveGen, Andes Biotech, Armata, Apis, Aptitude Vision, Atheln, Basilea, BioCurate, BioNtech, BridGene Biosciences, Burnet Research Institute, Capella, Celcuity, the Colorado State University Research Foundation, Cugene, Curegenix, Curon, Cyclacel, D.E. Shaw Research, Erimos, Eupraxia, EVOQ Therapeutics, Exo Therapeutics, Extend Biosciences, Genelux, Glyconex, HuyaBio, Hyamab, Immunicom, Immunoscape, InnoHealth Limited, Inven2, LBL Technology, Linnaeus, Lytix Biopharma, Maps Public Benefit Corporation, MaxCyte, Medicon, Neurolaxis, Neutrolis, Octagon, Orum, Oxford Biomedica, Pattern Computer, Phanes, PioTx, Prana, Protillion, Psychogenics, RDP Pharma, RefleXion Medical, REMD, Rubedo, Scimar, Serina Therapeutics, SimuRx, Stellate Biotherapeutics, Surf Bio, SymbioCellTech, ThermoFisher, TME Therapeutics, Vaccitech, Viotika, the Walter and Eliza Hall Institute, Western Oncolytics, Wex, Woebot Health, XCell Bio, Xylome, and Yingli. Deals I have worked on have included research collaborations, options, asset sales, licenses, territorial splits, and co-developments and co-promotions. These deals have included drug discovery platforms and drug candidates at stages from research to Phase I, II, or III clinical trials.

As business development consultants, my firm advises and assists clients with every aspect of partnering/collaborating. This includes strategy on when and how to partner/collaborate, making the best possible decks to convey the potential of an asset, making connections (outreach), providing advice on asset valuation, leading, advising, and drafting the negotiations of term sheets, and ultimately working with lawyers on contracts for the transaction. Even after a transaction closes, my firm often summarizes and explains the deal to company personnel so they understand their roles and obligations after the contract is signed. In addition, my firm often assists with delivering information and analyses to senior management and/or to the board as to the financial and non-financial implications relating to a proposed transaction.

In addition to my work guiding companies through licensing deals in the pharmaceutical industry, I have lectured or taught on all aspects of partnering, from scientific trends to asset evaluation and due diligence to licensing deal structures and deal trends, including at lectures and webinars for the Licensing Executive Society (the professional association of those involved in doing licensing deals), at many conferences (including Bio, BioEurope, and BioEurope Spring), and at the EBD Business Development Academy. Biotech and pharmaceutical companies, including publicly-traded companies, often contact me to provide training to their business development professionals on licensing due diligence evaluations, in-licensing, and negotiating licensing deals.

I have also reviewed research grants for the Australian equivalent of the National Institutes of Health (the Medical Research Futures Fund) and have served one prior time as an expert witness in an arbitration case (*NantCell, Inc., et al. v. Sorrento Therapeutics, Inc., et al.*, Case No. 01-19-0003-3950 before the American Arbitration Association) over a pharmaceutical licensing deal.

I am being compensated at a rate of \$600 per hour for my time in providing my independent opinions in this case.

## **CUSTOM AND PRACTICE WITH RESPECT TO PHARMACEUTICAL BUSINESS DEVELOPMENT AND LICENSING DEALS**

### ***The Purpose of Business Development and Licensing Deals***

In the pharmaceutical industry, partnership deals are a frequent way to bring two companies together to work to advance the discovery, development, and commercialization of drugs to treat diseases. Most commonly, the deal is between the company that owns the intellectual property (“IP”) of the drug (the originator and licensor) and a more established company (the licensee) that has the resources and expertise to apply to the further development and commercialization of that drug. The two parties sign a legal agreement (the contract) describing how they will work together and what rights and obligations they each have in the partnership.

Business development and licensing (“BD&L”) deals are a very important part of the prescription pharmaceutical industry. Individuals working in the industry often informally use the words “partnering,” “collaboration,” and “licensing” almost interchangeably, but a license is a grant of rights to the partner to exploit the invention of the originator and is a common component in partnerships and collaborations. The concept of a collaboration includes not just the license but also details the structure of how the parties to the deal will work together to maximize the value of the invention. Licensing deals and collaborations are a vital part of drug discovery and development in the pharmaceutical industry. Of the 691 new drugs (new chemical or biological entities as opposed to generic drugs) approved for marketing in the U.S. by the U.S. Food and Drug Administration (“FDA,” the regulatory agency that controls all prescription drug approvals) from 1963 to 1999, 38% were licensed to the company that obtained the approval for marketing the drug from the FDA.<sup>1</sup>

For licensees, collaborations reflect the reality that certain discovery research takes place in smaller companies and at universities. In my experience, a sizeable portion of the pipeline for these companies arises from collaborations with early stage companies. The licensee seeks to tap the best opportunities that fit their business growth strategies and sales force focus (whether that is selling prescription drugs to treat cancer, diabetes, or other diseases) and to reduce the very large risk of failure by doing these deals for what they judge as the most promising drug candidates. Indeed, most drug candidates in drug discovery and development fail, with 35% of projects in

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<sup>1</sup> DiMasi, J.A., “New Drug Innovation and Pharmaceutical Industry Structure: Trends in the Output of Pharmaceutical Firms,” *Drug Information Journal* 34: 1169-94 (2000).

research making it to Phase I clinical trials<sup>2</sup>, and less than 14% of those entering Phase I clinical trials making it to a marketing approval (by the FDA or equivalent regulatory authority for other countries).<sup>3</sup>

For the inventor or originator of the drug candidate, the partnership/collaboration can bring funds needed for the continued development of the asset. Clinical development (with Phase I, II, and III clinical trials) is expensive, with median clinical costs of almost \$1 billion per drug approval when one counts the cost of failures and the cost of capital (the value of money that could otherwise accumulate interest over time).<sup>4</sup> The partnership/collaboration can also use the licensee in providing expertise in development and commercialization, and resources not available at the licensor. The funds from a partnership/collaboration deal can also be used to build capabilities to enable successful commercialization at the licensor. In a partnership/collaboration, a young company/licensor can learn from the partner/collaborator and apply that experience to its other programs. There are statistics showing that partnering/collaborating reduces the risk of failure by as much as 30% versus going it alone.<sup>5</sup> Presumably this is both due to the experience of the licensee and to the ability to fund more studies rather than doing the minimal expenditure. This extra expenditure can mean increasing the chance of success by studying additional disease settings or indications.

A partnership/collaboration can also signal the quality of the licensor to investors (venture capitalists, investment bankers, and the public). The validation from a deal can help the licensor raise funds, as it is assumed that the due diligence evaluating the asset performed by the partner/collaborator is an assessment benefitting from deep knowledge of the disease and the requirements of successful development and commercialization.

In this case, the Collaboration and License Agreement between Novartis and Incyte dated November 24, 2009 (the “Agreement”), as amended, was such a BD&L deal. As reflected in its title, this Agreement reflects that it was a “collaboration” between the parties such that they would share in the commercial successes of the compounds covered thereby (JAK and c-MET, only the former of which is relevant to this litigation) in a meaningful, fair way.

### ***Financial Terms for a BD&L Deal***

As drug development is both risky and expensive, BD&L deals for the development and commercialization of drugs are structured with most of the payments spread out over time and contingent upon events increasingly demonstrating success (money now and bigger money later). The upfront payment is the one certain payment, not contingent upon the advancement of the drug. It is typically very important to the originator as it is money that can be used now for other things.

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<sup>2</sup> Paul, S.M. *et al.*, “How to improve R&D productivity: the pharmaceutical industry’s grand challenge,” *Nature Reviews Drug Discovery* 9: 203-214 (2010), at Figure 2 (multiplication of the probabilities of technical success p(TS) for all the steps in Figure 2 leading up to Phase 1).

<sup>3</sup> Wouters, O.J. *et al.*, “Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018,” *JAMA* 323(9): 844-853 (2020).

<sup>4</sup> *Ibid.*

<sup>5</sup> Nicholson, S. *et al.*, “Biotech-pharmaceutical alliances as a signal of asset and firm quality,” *Journal of Business* 78: 1433-64 (2005).

The in-licensor would like to minimize that “money out the door” and pay more when it is more certain the drug will be successful. The upfront payment is thus highly negotiated and varies widely from deal to deal even for the same stage of drug at the time of the deal.

Deals usually also have staged payments, called “milestones,” as the drug advances through development and approval for marketing. These may be development milestones (*e.g.*, at the start of Phase I, II, and III) and regulatory milestones (*e.g.*, a payment at approval for marketing in each of the U.S., Europe, and Asia), and these milestones are thought of as proportional to the removal of risk at each step. The milestones may also reflect a reward for leading and paying for costs of the stages of development. Another frequently used type of milestone are sales milestones, where there is a one-time payment typically upon the first achievement of a specified level (threshold) of sales. Sales milestones are frequently tiered and increase with higher sales thresholds. There can also be payments from the in-licensor for development expenses and these can be significant. The median research and development costs, including the capitalized cost of failed trials, are estimated as \$985.3 million per drug approval.<sup>6</sup>

Finally, there are royalties, a payment of a percentage of annual net sales (where net sales are sales after deductions of things like free samples and rebates). Royalties are typically tiered to have larger royalties with larger sales, thereby sharing success between partners/collaborators. The royalties are generally higher in deals where the drug comes into the deal at a more advanced stage of development. Royalties can be the largest financial component of a BD&L deal if there is a successful drug, because successful drugs can have peak sales of billions of dollars.

All these financial terms are negotiable and driven by the scope of the BD&L deal at issue, the roles and responsibilities of the partners, and the perceptions of potential value and risks of the drug’s development. There is expected to be sharing in the success of the drug proportional to the contributions. All of the financial terms can be traded off against other financial terms or changes in the deal scope, roles and responsibilities, and other items. Deal negotiators frequently make analogy to a balloon of value, where if you squeeze at one end, the balloon expands at the other end. We also speak of the various financial terms as multiple levers, multiple ways to shape the deal value.

### ***Process of Diligencing, Negotiating, and Finalizing a BD&L Deal***

There is an understood process to getting to a BD&L deal that pharmaceutical companies employ. First, potential partners will meet with one another, generally several times, to discuss the data and potential of the asset and its path to revenue, as well as the potential parameters of a possible partnership/collaboration and what they each bring to the table. Assuming the parties agree that the asset and potential deal structure could work, the diligence process will commence, with the larger pharmaceutical company exploring data and information relating to the compounds or drugs at issue, asking questions, assessing the risks, and planning the future continued development. Then the parties will migrate into the term sheet stage, where they will go back and forth on financial terms such as the license fee, milestones, and royalties, as well as other critical items like the scope of the proposed relationship and each party’s roles, responsibilities, and

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<sup>6</sup> Wouters, O.J. *et al.*, “Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018,” *JAMA* 323(9): 844-53 (2020).



expectations. During due diligence and negotiations, each party will engage in its own valuation analysis and will create financial models (often in Excel spreadsheets) of future costs and revenues to determine if the deal makes financial sense. Also throughout this process, with specifics dependent on the company, as a custom and practice there will be regular management, committee, and/or board meetings to give information updates and/or obtain requisite approvals. It is routinely the case that new approvals need to be obtained before a BD&L deal can be finalized if prior approval of terms change in any significant way. On the licensee company side, multiple layers of approvals may be required at different levels within the organization.

With respect to drivers of value, from the larger pharmaceutical company/non-originator's perspective, exclusive rights from the originator of the existing data, any regulatory exclusivity (such as orphan drug status), and the IP, including know-how and patents, are drivers of value. The know-how that is licensed may not be kept as exclusive (as eventually it will be discovered by others and published) and know-how is most significant at the beginning when the asset is being transferred. Hence, only rarely is know-how seen as a barrier to market competition against the drug. The exclusive licenses to patents are typically the biggest driver of deal value because the government grants the patent holder an exclusive right to sell, providing a barrier to competition. Regulatory exclusivities are similarly a value driver as the governmental regulatory agencies provide a barrier to competition by agreeing not to approve a drug in the same orphan indication, for example. Patents are generally viewed as the largest value driver.

In evaluating the investment, the payback timeframe (*i.e.*, when the cumulative cash flow coming in is equal to what has been spent) is often one of the considerations of the licensee pharmaceutical company in determining whether to proceed with the transaction. This is the point in time at which the investment begins to pay off; before that period there is no return. The payback timeframe is thus when the larger pharmaceutical company "breaks even." But BD&L transactions are not done to "break even" because a company seeks to generate meaningful profitability, so the larger pharmaceutical company must evaluate the risk in the context of the overall deal and the attractiveness or promise of the assets it is proposing to license.

Once the financial terms have been agreed to, a final term sheet has been exchanged, and the parties agree to move forward, the parties will migrate into the contract drafting stage, at which point legal counsel works to get the parties' agreements reflected in contract form. The business folks, however, will typically stay involved to ensure that the final term sheet is reflected in the draft contract and the business structure for success remains intact.

The above-mentioned BD&L team also routinely includes business consultants, financial advisors, and/or outside counsel for either or both of the parties to the BD&L deal.

From my extensive experience, I have observed and identified the existence of regularly recurring, generally accepted industry customs and practices in the pharmaceutical sector with respect to the form and trajectory of discussions and then negotiations, the process for internal corporate approvals for proposed transactions, the use of valuation analysis, financial modeling, and other projections, the common structures applicable to licensing, and other core economic terms, as well as industry terminology and shorthand phrases used for contract terms and

conditions, to describe certain events, or to express certain concepts. All of this informs my opinions, set forth below.

### OPINIONS

**I. As used in the Agreement between Novartis and Incyte, based on my experience and industry custom and practice, “Licensed Patent Rights” encompasses all patent rights, irrespective of which party to the Agreement obtained or owns the applicable patent(s).**

**A. The duration of a royalty stream in a pharmaceutical licensing agreement is typically tied to loss of market exclusivity, including patent protection; as such, if the duration of the reverse royalty was going to somehow deviate from the norm, that would have been clearly reflected in the parties’ Agreement, but no such deviation is clearly identified. To the contrary, the technical terms and structure of the Agreement reflect that the duration of the reverse royalty being paid by Incyte (just as the duration of the regular royalty being paid by Novartis) takes into consideration all possible avenues of exclusivity protecting the product from market competition by third parties.**

In the pharmaceutical licensing context, royalties are paid to share in the economic success of a pharmaceutical product covered by an agreement between two counterparties. Royalties are a negotiated percentage of sales (routinely a percentage of net sales, where certain items such as rebates are taken out of the sales before the royalties are calculated) and can be flat or more commonly tiered upward with increasing sales. Here, in Section 8.3 of the Agreement, the parties agreed to tiered royalty structures, both for the royalties Novartis pays to Incyte for ex-U.S. sales (as set forth in Section 8.3(a)) and for the reverse royalties Incyte pays to Novartis for U.S. sales (as set forth in Section 8.3(b)).

Many deals in the pharmaceutical industry involve exclusive rights in a country or region. The general industry custom for exclusive pharmaceutical licensing deals is that royalties are paid at the negotiated royalty rates as long as there is market exclusivity in that country or region that prevents competition with the party selling the same drug as a generic (*i.e.*, selling of the same drug by another party not part of the licensing deal in question). This is because it makes sense to pay royalties to your collaborator while you are dominating the market due to your exclusivity status and with the ability to exclude competition by patents and/or regulatory exclusivity; this is the time when there are much higher sales, at a higher price, for the company selling the drug in a given county or region than is possible after generics come into the market. Following generic entry into the market, the brand name manufacturer will often lose the majority of sales in a single year. Generics significantly decrease both the sales volume of the brand name manufacturer as well as the sales price per unit, meaning they reduce the profit margin on those sales. It is for this reason that royalties are commonly paid in full until generic entry; paying full royalties after generic market entry would disproportionately burden the royalty payor given their significantly reduced profit margin for that drug.



The term, or duration, of royalties paid in pharmaceutical licensing agreements are frequently tied to market exclusivity, with exclusivity provided by patent protection and/or regulatory exclusivities, as may be applicable. Patents are filed on new inventions (as Incyte did with the JAK compound), and in return, governments in most of the world grant 20 years of exclusivity to the invention, prohibiting others from marketing and selling the same invention as covered by that patent. An alternative or complementary form of exclusivity is provided by regulatory exclusivity. Regulatory authorities such as the FDA and the European Union European Medicines Agency (EMA), whose approval is necessary to market the drug, provide orphan drug exclusivity (for example), where they aim to encourage the creation of new drugs for diseases with smaller patient populations and thus agree to prevent a generic copy of the new drug for that same orphan disease for a period of years. The orphan drug exclusivity only prevents a generic copy from entering the exact same disease population that was the basis for orphan status. In the U.S., orphan drug exclusivity is seven years, and in Europe, orphan drug exclusivity is 10 years. Many countries (such as China) have no orphan drug exclusivity. Thus, in my experience, patent protection is offered in more countries and is a broader protection, with composition of matter (or compound) patents prohibiting use of the drug other than to the patent holder or the patent holder's licensee. Patents may also be a longer duration of market exclusivity, particularly in the U.S. and Europe where a valid compound patent is obtained and enforced (but not necessarily in all other markets).

In describing the duration of royalty payments, it is customary for the exclusivity behind the royalty to be determined on a product-by-product basis (rather than on a bundle of products) and on a country-by-country basis, meaning that royalties are paid for each product where the exclusivity (provided by the patent or by the regulatory authority such as the FDA) exists in that country. This allows royalty payments to properly reflect the status of the market in that country as to that product.

The Novartis-Incyte transaction reflected in the Agreement involved exclusive rights but also a territorial split as to the JAK compound, with Incyte responsible for sales in the U.S. and Novartis in all ex-U.S. countries. (Novartis became responsible for c-MET compound sales worldwide.) Against that backdrop, Section 8.3(c) of the Agreement – which explains the duration of royalties to be paid by either party, irrespective of compound – is a very standard royalty duration provision in the pharmaceutical licensing space. Similarly worded and structured provisions are regularly found in pharmaceutical licensing agreements calling for the payment of royalties. The purpose of these types of provisions is to specify both the end of a royalty term and when a party may potentially be able to reduce the amount of royalties it pays.

With respect to the duration of a royalty term, it is customary for royalty term provisions to provide that royalties must be paid until the expiration of patent rights (which provide the strongest and often longest protection from competition) and oftentimes also the expiration of regulatory exclusivity, if that happens to be longer in a particular country. The reason these two categories are often included as potential endpoints for the royalty term is because both patent protection and regulatory exclusivity provide the royalty-paying party a manner of maintaining market exclusivity. And with market exclusivity, the entity selling the drug in a relevant market maintains higher sales and higher profits because there is no generic entry to erode the price and reduce the sales of the licensed product, as previously noted. It is also customary for royalty term

provisions to provide for royalties on at least ten years' worth of sales, based on the standard sales curves that would apply to an average pharmaceutical product. Section 8.3(c) of the Agreement between Novartis and Incyte follows this common form, where full royalties are to be paid by the royalty-paying party until the later of (1) last valid patent claim, (2) 10 years of sales, or (3) expiration of regulatory exclusivity in a given country.

In 2009 when the Agreement was being negotiated and was ultimately signed, Incyte was the only party who had filed patent applications and was actually granted a composition of matter patent relating to the JAK compound, as reflected on Exhibit A-2 to the Agreement. Indeed, by Phase III – which is where Incyte was at with the JAK compound when it entered into the Agreement – Incyte would have had patents or patent applications pending because Incyte would want that protection from competition to protect the value of its asset and only the first-to-file on a new invention is eligible to get a patent. In the pharmaceutical industry, granted patents exclude anyone not licensed by the patent holder from marketing the invention for 20 years from filing of the patent (plus some possible extension for review time). The most valuable patents are those on the drug's composition of matter (the chemical ingredients of the drug), preventing another party from selling the same molecule for any use. A composition of matter patent granted for the first synthesis of a molecule prevents any use of that molecule unless under an agreement (a license) to market a product using the patent. Composition of matter patents are listed in what is called the Orange Book in the U.S., letting third parties know when the patents that block market entry expire. The developer of a drug also works to establish additional patents; however, these are seen as less of a barrier to competition than composition of matter patents. And here, Incyte obtained a JAK composition of matter patent from the U.S. Patent and Trademark Office, which was Orange Book listed, on October 6, 2009, before the Agreement was signed.

Section 8.3(c) of the Agreement references as its first endpoint the expiration of “Licensed Patent Rights.” Consistent with my experience and the industry custom and practice discussed above of tying the payment of royalties to market exclusivity, I read the term “Licensed Patent Rights” as encompassing all patent rights that are owned by *either* Incyte or Novartis, or both of them, and that there is no limitation or contingency on which patent rights can be used to calculate the duration of the royalty term applicable to a particular royalty (including the reverse royalty) being paid.<sup>7</sup> This pattern of including all relevant IP in calculating royalty duration is common in a territorial split agreement, as the parties want to have all IP in the agreement so no IP owned by one party or the other blocks either party from maximizing the product opportunity (and sharing that success with its partner/collaborator). This is also consistent with the definition of the word “Covering,” also used in Section 8.3(c)(i), which is a commonplace definition used in the industry and would be interpreted by pharmaceutical industry professionals such as myself as meaning that

<sup>7</sup> In ruling on Incyte's motion to dismiss Novartis' complaint, I understand that the Court held, in examining only the face of the Agreement and the parties' respective written submissions at the outset of that case, that “clause (i) of Section 8.3(c) of the Agreement suggests more than one meaning” such that this “provision of the Agreement is ambiguous.” Docket No. 52 at 24. From my industry perspective, I respectfully interpret the term “Licensed Patent Rights” and clause (i), particularly in the context of the overall Agreement, as facially clear. It is, from my reading, the existence of patent rights subject to being licensed under the Agreement, not the identity of the licensor or licensee, which explains the word “Licensed” being used in “Licensed Patent Rights.” As such, so long as such patent rights are in existence and protecting a subject pharmaceutical product from market competition from a third party outside the Agreement, as clearly is the case with respect to Jakafi in the United States, then Jakafi is “Covered” by Licensed Patent Rights in the U.S.

the applicable patent protects the product from market competition by a third party that is not party to the agreement. Necessarily, the U.S. composition of matter patent Incyte had obtained relating to Jakafi in October 2009 would fall within the scope of “Licensed Patent Rights,” as would any other U.S. patents Incyte obtained.

Based on my industry experience and industry custom and practice, if the parties had intended to exclude Incyte’s existing patents and patent applications (as set forth on Exhibit A-2 of the Agreement) from the definition of “Licensed Patent Rights” or endpoint (i) in Section 8.3(c) for purposes of determining the duration of the reverse royalty’s term, that would have been made clear in the Agreement, so as to avoid any misapprehension that endpoint (i) of Section 8.3(c) had its customarily broad application. In other words, I would expect that given industry norms, such a limitation – or put differently, the contingency of Novartis having to get its own patent to ever be able to satisfy endpoint (i) of Section 8.3(c) – would have been clearly spelled out given that it is a variance from industry custom and practice and thus expectation. However, here, such a limitation/contingency is not identified anywhere in the Agreement or any contemporaneous material I have seen in the record.

Further, based on my industry experience and industry custom and practice, if the parties had intended for the reverse royalty term to have different parameters or endpoints than the term applicable to the royalties being paid by Novartis to Incyte, then the parties would have clearly spelled that out, just as they did when describing the royalty rates in Sections 8.3(a) (royalty rates to be paid by Novartis to Incyte) and 8.3(b) (reverse royalty rates to be paid by Incyte to Novartis). Instead, however, the parties agreed to one reciprocal provision, Section 8.3(c), to govern the duration of all the royalties described in the previous two sections of the Agreement.

**B. The shorthand, terms of art, and other language used by the parties in communications between each other and in internal communications discussing the royalties reflect a commercial understanding that each party’s royalties would be paid at the full negotiated royalty rates until the loss of market exclusivity in the applicable country, consistent with industry custom and practice, and thus support my opinion.**

As explained above, custom and practice in the pharmaceutical industry with respect to paying a royalty is that it is to be paid until the royalty payor no longer has market exclusivity in the relevant market; generally, that is tied to the expiration of patent protection for the given product. The members of the Novartis and Incyte deal teams, management Committees, and Board of Directors were all experienced professionals in the industry; they would have been aware of this custom and practice, and would approach any discussion of royalties with an assumption that the customary rules and terms applied unless negotiated or stated otherwise.

The parties’ term sheet exchanges and respective internal management presentations and related materials do not reflect that the parties were deviating from custom and practice with respect to the reverse royalty to be paid by Incyte to Novartis. To the contrary, they all reflect that the parties treated the duration of both royalties being paid here (*i.e.*, the royalties paid by Novartis to Incyte and the reverse royalties paid by Incyte to Novartis) in the same way. Moreover, there are terms of art and other industry references in the documents that signal to an industry

professional that the parties were indeed following this custom and practice. These include the following:

The term “LOE” is referenced periodically in the Novartis Committee presentation materials and other contemporaneous internal Novartis documents. In the industry, “LOE” or “Loss of Exclusivity” is used to connote when the person selling the drug no longer has market exclusivity—which in most countries (and certainly in the U.S. and the E.U.) is typically when patent protection has expired. Loss of patent exclusivity is the most common basis for loss of market exclusivity, along with the less common regulatory exclusivity, a term actually used in the Agreement to define other non-patent exclusivities that may exist to protect a drug from competition. Novartis’ use of “LOE” prior to the Agreement’s execution reflects that Novartis was following industry custom and practice as far as evaluating the duration of the royalty streams being paid in either direction.

Both sides specifically referred to the royalty from Incyte to Novartis as a “*reverse royalty*,” a term then used in Section 8.3(b)(i). Where royalties are paid in pharmaceutical licensing contracts, generally they are paid by the licensee to the licensor as compensation for being granted the right to use the IP. The term “*reverse royalty*” is an industry term understood to describe the scenario where the IP *licensor* is the party who will be paying the royalty to the IP *licensee*. Among other areas, I have seen these types of royalties (not necessarily called reverse royalties) used in territorial split contracts because the parties are paying royalties to one another given their respective contributions to the overall relationship.

Here, the parties’ express use of the term “reverse royalty” signals to someone in the industry that the royalty from Incyte to Novartis was being paid in the opposite (reverse) direction, being paid by the patent owner understanding that the patents (or pending patent applications) protecting or relating to Jakafi in the U.S. were Incyte’s, as reflected in Exhibit A-2 to the Agreement. Had the parties understood that Incyte’s already-developed IP was not to be used in calculating the duration of the reverse royalty, and that Novartis was only to receive a 10-year income stream which might theoretically be extended should Novartis successfully secure its own U.S. patent covering Jakafi and license it to Incyte, the parties would have referred to that royalty by using a different term and/or layered in the necessary caveats in the Agreement. That difference in calculating the duration would also be clearly separated out or distinguished in different sections of the contract, as the different royalty rates are separately set out in Sections 8.3(a) and 8.3(b) of the Agreement. But no such separation or distinguishing was done here.

Incyte and its advisors also referred to the reverse royalty in some internal documents as a “clawback.” Based on my experience in the industry and familiarity with the language used by pharmaceutical licensing deal negotiators, the use of this term suggests an understanding of the reverse royalty as a mechanism for Novartis to get back some of the significant value it was paying to Incyte, for example, in the double-digit royalties on Novartis’ ex-U.S. sales relating to the JAK compound. In other agreements I have reviewed, the term “clawback” is used to connote a reimbursement, recoupment/repayment, or recapture of funds or value, including in the royalty context when claiming entitlement to reimbursement of royalty payments in certain delineated circumstances such as a patent challenge.

My opinion in this regard is reinforced by my review of additional internal Incyte documents, such as Board of Directors presentations, in which Incyte described the reverse royalty rates as effectively reducing the percentage rates of the Novartis royalty to Incyte (*e.g.*, describing the Novartis rates for paying Incyte as 18-24% “less” or “net against” the reverse royalty rates of 2-5%). If the reverse royalty is properly viewed through that lens—*i.e.*, as a “clawback” of some portion of the Novartis royalties being paid to Incyte—then commercial logic would suggest that the “clawback” would continue for approximately the same length of time that Novartis was continuing to pay royalties to Incyte, consistent with that interrelationship.

In any event, the absence of any differentiation as to the duration of the reverse royalty in both the Novartis and Incyte (or its advisors’) documents suggests to me, based on my industry experience, that royalties were meant to be paid by each party for the same time period—*i.e.*, until the expiration of market exclusivity and necessarily patent protection. That would mean that Incyte would pay royalties to Novartis on U.S. sales as long as patent protection gave Incyte market exclusivity. In my experience, if there was in fact going to be a differentiation of the duration of the reverse royalty being paid by Incyte, that would be clearly reflected in the contemporaneous documents, including in the Committee presentations on Novartis’ side and in the Board of Directors presentations on Incyte’s side. No such differentiation was ever made, suggesting that the customary duration (until loss of market exclusivity) would apply.

In my experience, if the receipt of a royalty for a particular timeframe was conditioned on undertaking an additional step, like Novartis obtaining a patent that protects Jakafi in the U.S., that would be clearly reflected in not only the contract but also the contemporaneous documents. By way of example, the Committee presentations on Novartis’ side would reflect that Novartis needed to take that step in order to ensure more than 10 years’ worth of reverse royalties based on U.S. sales. Similarly, the Board of Directors presentations on Incyte’s side would reflect that Incyte’s window to pay reverse royalties would be limited to ten years *unless* Novartis took that next step. No such “condition” of seeking new IP is reflected anywhere in the contemporaneous internal documents.<sup>8</sup>

Additionally, had this limitation/contingency also been agreed upon by the parties at the time of Agreement execution, it would be expected to be the topic of discussion at joint Committees following execution of the Agreement and/or internally within Novartis as Novartis would have been incentivized to go get any patent, no matter its real value. However, I have not seen anything in the record to support that this ever occurred; in fact, just the opposite is true.

<sup>8</sup> An example of what I mean by clearly reflecting such a condition in the contract is provided by Section 8.3(b)(ii), which provides that an additional 1% royalty will be paid by Incyte to Novartis only “If Covered by Novartis Improvements.”



**C. The final, agreed-upon term sheet reflects that the duration of the royalty stream going in each direction would be calculated in the same manner; there is no limitation or contingency with respect to patent rights when calculating the duration of the reverse royalty to be paid by Incyte. Moreover, it would be expected that any attempt by Incyte to shorten or condition the duration of the reverse royalty following the final term sheet and in the contract drafting stage would have been the subject of extensive discussion, which did not occur.**

**1. Royalties being paid and received, including the duration thereof, are material financial deal terms to be settled in the term sheet stage.**

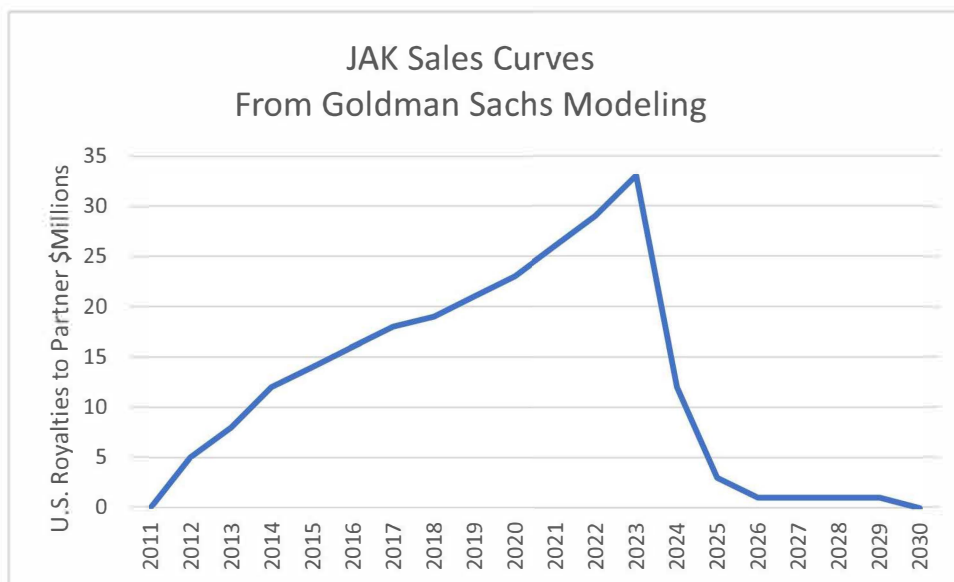
Custom and practice in the pharmaceutical industry in negotiating a collaboration and license agreement is to employ term sheets to negotiate and settle material deal terms prior to moving to the phase of drafting a contract. These term sheets will include the core financial terms, including royalties to be paid and the duration of time for which they will be paid, and are meant to allow the parties to reach agreement on core terms where disagreement might make them decide to part ways. While the final term sheet is technically not binding, as a practical matter it defines the contract and reflects that the parties have a “deal” and thus are in agreement on the financial terms and other critical issues.

In my experience, the inclusion of a financial term in a term sheet shows that it was considered a material term to both parties. Royalties are typically the largest potential payments in a license for a drug in pharmaceutical deals. Here, the two parties treated the royalties to be paid by each side as very important, each repeatedly proposing and countering on both sets of royalties, with changes in several term sheets until the final royalty terms were agreed upon. Incyte’s initial reluctance to agree to pay a reverse royalty to Novartis, as seen in the first term sheet response Incyte sent back to Novartis, further reflects that it was a material financial deal term.

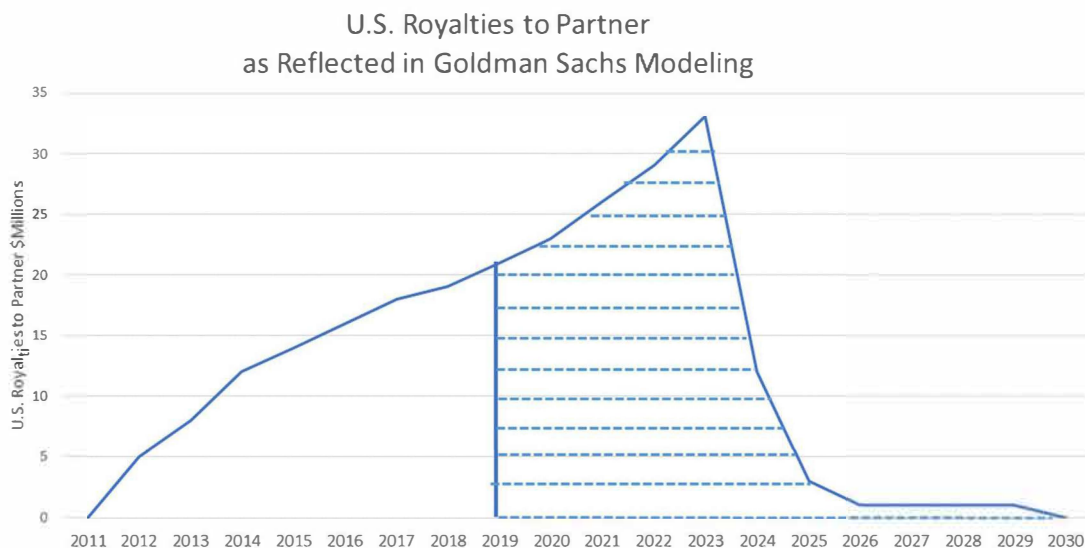
In my experience, for a potential partner in Novartis’ position, with the risk adjusted deal value forecast to be below the threshold and benchmark value splits reflecting the relative contributions of the two parties, and with the estimated time to break-even being so long (approximately a decade), every negative change in deal terms would seem critical. If the risk adjusted value is already seen as below the threshold and benchmark value splits, any further lowering in financial terms would likely be unacceptable. Although it was hoped that the products covered by the Agreement would be approved and commercially successful ex-U.S., there was still much uncertainty because limited, if any, regulatory discussions had been accomplished.

In my experience, and pursuant to industry custom and practice, the duration of time a royalty will be paid is a core financial term (just as is the royalty rate) because it has a critical impact on how much money will be paid overall in royalties. Because the typical drug sales grow over a period of multiple years, and the royalties are typically tiered upward so that a higher percentage is paid on higher sales, the royalties paid increase each year up to the peak of the drug sales. In the final model Goldman Sachs created for Incyte (as its financial advisor), Goldman Sachs forecasted sales peaking in 2023 before declining, which I graphed below (based on Exhibit 17 from Marshall Smith’s deposition).





Using the Goldman Sachs forecast for the reverse royalties, I also graphed the royalties forecast over time (below), with the area under the curve marked with blue bars/shading reflecting the reverse royalties being paid by Incyte in 2019 and beyond. The royalties to be paid rise more steeply over time than sales (as the royalties tier up with sales), but also were forecast to peak in 2023. Clearly, years *beyond* 2019 were an important part of the forecasted value of the reverse royalties to be paid by Incyte to Novartis. Changing the duration changes the total value of these royalties substantially.



2. **Ultimately, however, the final term sheet will reflect the parties' agreement on core financial terms based upon their own respective valuation analyses and will be used to generate the contract. This will include the duration of any royalty, as the duration thereof is inextricably intertwined with the agreed-upon royalty rate to be paid by the royalty payor. The final term sheet, dated July 9, 2009, clearly describes the duration of reverse royalty.**

Following multiple exchanges of term sheets, Novartis sent its fourth term sheet to Incyte on July 9, 2009. I understand this to be the last term sheet exchanged between the parties before Incyte sent Novartis a draft contract on July 28, 2009 and that both sides referred to the July 9, 2009 term sheet as the "final" term sheet; indeed, Incyte itself used the term "final" in presentations to its Board of Directors.

The July 9, 2009 term sheet clearly sets forth the royalty rates the parties agreed to pay one another in the Royalty (c-MET) and Royalty (JAK) sections (*i.e.*, the c-MET royalties to be paid by Novartis to Incyte, the JAK ex-U.S. royalties to be paid by Novartis to Incyte, and the JAK U.S. reverse royalties to be paid by Incyte to Novartis), while also noting that Incyte need not begin paying JAK royalties to Novartis until Novartis received certain reimbursement and pricing approvals in the E.U. This permitted the parties to effectively begin paying one another JAK royalties at the same time.

The July 9, 2009 term sheet then clearly sets forth how to calculate the royalty term for all royalties being paid under the Agreement, irrespective of compound and who is the royalty payor or payee. It describes duration to be calculated on a product-by-product, country-by-country basis and to go until the longest of three potential endpoints, with the first one being "expiration of the last to expire Valid Claim Within Licensed IP." While "Licensed IP" is defined in the term sheet to cover both patents and know-how (including Incyte's patents), "Valid Claim" is separately defined as clearly relating to patents. Accordingly, I read "expiration of the last to expire Valid Claim Within Licensed IP" to mean the last-to-expire patent claim protecting the product, consistent with industry custom and practice. The second and third potential endpoints are 10 years from first commercial sale and expiration of regulatory exclusivity, also consistent with custom and practice in the industry, as noted above. These terms are so customary that in early term sheets industry BD&L professionals may write something akin to "term: last valid claim or 10 years from FCS" as shorthand for the more complete legal language, as experienced BD&L professionals will understand this as standard form.

3. **In short, both the rates and the duration of the JAK royalties to be paid by Novartis to Incyte, and the rates and duration of the reverse royalties to be paid by Incyte to Novartis, are clear from this final term sheet and calculated the same way. While certain Incyte witnesses, namely Messrs. Hoppenot and Mikkelsen, have suggested the term sheet was unclear as to the duration of the reverse royalty, as discussed in more detail below, I disagree as the final term sheet was clear on its face. Even Incyte's outside counsel Steven Singer conceded at his deposition (Tr. 112:23-113:17) that the final term sheet did not require Novartis to obtain any IP in order to benefit from endpoint (i) regarding valid patent claims covering the product in the U.S. This mutually constructed final term sheet would have allowed both sides to conduct their separate valuation analyses, confirm they are in agreement on these material terms, and agree to move on to the contract drafting stage. I read the final term sheet and the final draft of the contract to be consistent in both form and substance, as is customary and expected in these types of deal negotiations.**

Section 7.3 of the first draft of the contract Incyte prepared and sent to Novartis is structured and worded very closely to the Royalty (JAK) and Royalty Term sections of the final term sheet.

The final term sheet included a "Royalty (JAK)" section which listed the royalty rates to be paid by Novartis first and the reverse royalty rates to be paid by Incyte second, followed by a "Royalty Term" section specifying the duration of royalties being paid under the Agreement and the conditions for invoking a 50% reduction in royalty payments where applicable. These "Royalty (JAK)" and "Royalty Term" sections are effectively boxes in a chart above one another and work off one another. The first draft of the Agreement tracks the final term sheet closely in both structure and wording. Sections 7.3(a) and (b), respectively, set forth the Novartis-paying royalty rates and the Incyte-paying reverse royalty rates, just like the "Royalty (JAK)" section of the final term sheet. And Section 7.3(c) of the first draft of the Agreement sets forth the duration of both parties' royalties and the conditions for invoking the 50% reduction, using wording almost identical to that in the "Royalty Term" section of the final term sheet. Everything stated in this paragraph is also true when comparing the final term sheet to Section 8.3 of the final Agreement. The percentage rates of the Novartis-paying royalty and the Incyte-paying reverse royalty are the same in the final term sheet and the contract.

The only difference I have identified between the final term sheet and the contract as far as the royalty term is the change of the term "Licensed IP" to "Licensed Patent Rights." It is my opinion that this does not reflect an intentional substantive change as far as calculating the duration of the reverse royalty. Additional legal review may result in slight wording changes, but reducing the duration of a royalty stream by a matter of years goes beyond a matter of refinement and would represent a substantive change to financial deal terms and to financial valuation.

I understand that Douglas Hager, one of the two lead negotiators for Novartis, testified at his deposition (Tr. 316:6-318:19) that he had a conversation with Steven Singer, Incyte's outside deal counsel, in which Mr. Singer explained that he changed the term "Licensed IP" to "Licensed Patent Rights" in Incyte's first draft of the Agreement to be more precise, given that "IP" includes both patent rights and know-how, but only the former have expiration dates. Thus, according to

this testimony, the purpose of the change was simply to confirm that the royalty term would be measured by the life of patent protection (not the eternal life of know-how)—it was not intended to limit whose patents would be considered for purposes of calculating the royalty term. This explanation for the change from “Licensed IP” to “Licensed Patent Rights” makes perfect commercial sense to me, as measuring the royalty term based on the existence of know-how would, in my experience, have been unusual and not the more typical custom and practice. It also makes sense in the context of looking at the history of term sheets, where the parties aimed to have an endpoint for the payment of royalties to one another, and paying royalties on know-how would last as long as sales occurred. Moreover, there is nothing in the record on either side suggesting that either Novartis or Incyte was viewing know-how to affect the duration of the royalty stream in either direction.

The change from “Licensed IP” to “Licensed Patent Rights” thus appears, in my opinion, to be a non-substantive refinement, which is the type of change that is customarily made at the contract drafting stage. Apart from the change of this defined term, there is very little relevant refinement or wordsmithing with respect to the royalty provisions between the final term sheet and the final contract. This signals to me, based on my experience and familiarity with the negotiation process, that the parties were in fact adhering to the agreed-upon term sheet, as is customary and expected in these types of deal negotiations.

**4. Having gone through multiple rounds of term sheet negotiations to work out the core financial deal terms, in my experience, and pursuant to industry custom and practice, one would not generally “go backwards” by renegotiating the duration of the reverse royalty in the contract drafting stage given that it would affect valuation analysis. Had this occurred, however, it would be the subject of discussion and renewed valuation efforts and negotiations, which did not occur.**

In my experience, while it is true that term sheets are “non-binding” in that the final contract is what “binds” the parties to their deal, attempts to renegotiate material deal terms that were included in the term sheets at the contract drafting stage are viewed unfavorably (and seen as almost unfair). Because they are surprises, such renegotiations are invariably the subject of significant comment both internally and between the parties. For example, I would expect to see internal debate about *whether* to even propose such a change in communications at the time, and would also expect to see emails between the parties discussing such proposed changes or notes of meetings or verbal discussions where such proposed changes were discussed. While changes can and do come up as parties see the whole of the agreement and sometimes thus reconsider positions, these sorts of changes result in active discussions, would generally be documented in issues lists exchanged between the parties, and could indeed derail the deal.

Notably, there is no discussion of the duration of the reverse royalty owed by Incyte to Novartis (let alone a change thereto) on any of the issue lists exchanged between the parties during the contract drafting stage of this deal. Nor is it listed on internal charts, descriptions, or management or Board presentations reporting on the progress of the contract drafting discussions or the parties’ meetings. The duration of a royalty to be paid is a material deal term that would affect valuation analysis. Its absence in presentations is consistent with its form being very standard and settled. It would have been highlighted or at least mentioned had the duration of the

reverse royalty in fact been recalibrated during the contract drafting stage, as Incyte alleges. I have not seen anything to suggest that this occurred, and Incyte's witnesses conceded that they did not recall such discussions having taken place. If the parties had renegotiated and a significant financial term change was introduced since the final term sheet, the expectation based on custom and practice was to obtain new management, Committee, and/or Board approvals due to that change. But none are reflected in the record.

In fact, the custom of trying to create a full agreement adhering to the agreed-upon deal terms in the term sheet is reflected in the cover email accompanying the first draft of the contract Incyte drafted and sent to Novartis on July 28, 2009. In that email, Incyte's Dan Maravei says "[w]e also hope you will find that we adhered thoroughly to the term sheet as we last discussed it." NOVARTISPROD000001349. Nothing in the contemporaneous record suggests that Incyte was anything but true to the agreement on deal terms reached by the parties in the term sheet.

**D. Both the Agreement's structure and technical language as to patents and the practical improbability of Novartis obtaining new and additional U.S. patents to assist Incyte in its commercialization of Jakafi further support my opinion.**

The Agreement as a whole indicates that Incyte, as the innovator, had sought wide-reaching patent protection with respect to its compounds before Novartis even came into the picture as a viable partner. To that end, the various JAK patent applications, including for the composition of matter patent it had sought and obtained pre-Agreement, are listed on Exhibit A-2 to the Agreement. Incyte also negotiated to ensure that it was the party leading the charge on JAK patent prosecution and maintenance activity with respect to its invention, as reflected in Section 7.2 of the Agreement, specifically carving out the INCY0039 Patent Rights worldwide. In short, on the face of the Agreement, Incyte had already pursued patent protection for Jakafi in the U.S. that would provide Incyte (as the seller in this territory) market exclusivity as to third parties outside the Agreement. And where it was contemplated that Novartis may potentially improve upon Incyte's IP by developing its own, Incyte agreed to pay Novartis a separate royalty for that additional effort. *See* Section 8.3(b)(ii) (additional 1% royalty will be paid by Incyte to Novartis only "If Covered by Novartis Improvements"). "Novartis Improvements" is not included in describing the tiered royalty rates on U.S. sales in Section 8.3(b)(i), nor does that section say anything about Novartis obtaining a patent. The same is true of Section 8.3(c).

Practically speaking, obtaining a patent that will assist in the commercialization of a drug is not a simple feat. Where a party has already obtained a composition of matter patent and sought various other patents, as Incyte did here, the need for any additional patent protection is lessened. The notion that Novartis should obtain a new and separate U.S. patent that covers Jakafi as that product is approved for sale in the U.S. and then license that new patent to Incyte to aid in Incyte's commercialization effort – and necessarily get more than ten years' worth of reverse royalties – is practically improbable but also would have little incremental value from a commercial and market hold perspective given the IP Incyte already had. A company in Novartis' position would not have agreed to such a speculative contingency to dictate the potential longest duration of a royalty it is being paid.



**II. Based on my experience and industry custom and practice, it makes commercial sense for “Licensed Patent Rights” to encompass all patent rights, independent of which party to the collaboration is the patent holder, in determining the duration of the reverse royalty term.**

**A. Collaborators like Novartis and Incyte are to share in the upside of their commercialization efforts of a drug, and here Novartis provided many contributions which ultimately benefited the development and commercialization of Jakafi in the U.S.**

In my experience, it is custom and practice in the pharmaceutical industry for collaborators who agree to partake in a territorial split to structure their business relationship and cooperate with one another, effectively as a joint team, such that they can share in the upside that results from the product’s coordinated commercialization worldwide. In doing so, all parties—in this instance, Novartis and Incyte—benefit and their interests are aligned in ensuring the product’s global success. As Todd MacLaughlan testified at his deposition (Tr. 64:19-65:16, 231:13-232:5), this “alignment between Novartis and Incyte” was necessary so that both sides’ efforts could “maximize” global success; consequently, “the sales in the U.S. are not only the result of what Incyte does, it’s the result of what happens to the asset as a whole no matter who owns it.”

As part of its collaboration with Incyte, Novartis made several material contributions that were highly beneficial to Incyte, and ultimately, to Incyte’s sale of Jakafi in the United States. At the outset, Novartis was obligated to make a \$150 million license fee payment upon signing the Agreement, and to pay tens of millions more in clinical study costs and milestone payments within just the first several months of the collaboration. In my experience working with growth-stage, small pharmaceutical companies, those payments would have served as an immediate and important benefit to Incyte, particularly given that Incyte did not at the time sell any pharmaceutical products, had a significant accumulated deficit and a significant amount of debt, and so needed that funding to launch Jakafi in the U.S. Incyte’s own 10-K filings to the U.S. Securities and Exchange Commission for the years ended 2008 and 2009 confirm as much, noting an accumulated deficit well over a billion dollars, the “need [for] additional capital in the future,” Incyte’s “large amount of debt,” and that as of December 31, 2008, Incyte “d[id] not expect to generate product sales from [its] drug discovery and development efforts for several years, if at all.” Todd MacLaughlan, Novartis’ lead negotiator, similarly testified to this, noting that “it was very important for Incyte at that time to have money upfront. They had some issues. So the deal was structured so that a lot of the upfront monies would go to Incyte, because they had overhead and other things, and a lot of the back-end money would go to Novartis.” Tr. 48:10-18. Mr. MacLaughlan also testified that “Incyte was concerned about spending money, and they wanted to make sure they could stay solvent.” Tr. 155:14-25.

In the Agreement, Novartis took on the costs relating to multiple clinical studies, directly benefitting Incyte, and participated in or lead these clinical trials. For example, Novartis paid 50% of the out-of-pocket costs incurred in conducting the clinical study with the proposal number INCB 18424-351 (study 351), including payment of \$1.8 million for Incyte’s out-of-pocket expenses, and a \$60 million milestone payment. Further, Novartis became solely responsible for conducting the clinical study with the proposal number INCB 18424-352 (study 352), and fully reimbursed



Incyte for costs it had incurred up to the signing of the Agreement, which was at least \$5.5 million. The data and results of these clinical trials were ultimately used to secure regulatory approvals.

Novartis also contributed, among many other things, additional financial contributions, significant development costs, technical and industry expertise, a global outreach and scale of organization, and Novartis' relationships with regulatory agencies, thought leaders, and other third parties, to which Incyte otherwise may have had no or limited access. Incyte itself has acknowledged Novartis' many contributions to the commercialization of Jakafi in the U.S. (INCY000119691-92 and INCY000028285).

In my experience, it would be economically unjustifiable, given the other financial terms that Incyte had demanded including significant milestones and high royalties, for Novartis to enter into a collaboration whereby it provides such significant value and pays such significant milestones and high royalties on ex-U.S. sales over time, without structuring the deal such that Novartis obtains some reciprocal financial benefit of all of this to enable a fair compensation and value split; the parties agreed in the Agreement that the method of Novartis recouping value would be via royalties on U.S. sales on the back end.

**B. There is no commercially rational basis to limit “Licensed Patent Rights” to exclude Incyte’s patents protecting Jakafi in the U.S.**

Based on my experience and industry custom and practice, it makes commercial sense for “Licensed Patent Rights,” as defined in the Agreement, to encompass all patent rights—irrespective of who within the collaboration owns the patent—because that is the only reading of the term that is consistent with the basis and rationale for parties like Incyte and Novartis to collaborate at all.

Incyte had discovered the compounds and sought patent protection for same, including in the U.S., as reflected on Exhibit A-2 of the Agreement; this is why Novartis was willing to enter the Agreement in the first place. Novartis had no patents or patent applications covering those compounds, nor should it have as it was not the inventor and had no relationship to them prior to the Agreement. Accordingly, at the time of contract execution, the only patent rights that could have been considered as “Licensed Patent Rights” were Incyte’s.

Incyte demanded, among other things, significant milestones and royalties on ex-U.S. sales, and so Novartis in turn asked to be adequately compensated for its contributions to the commercial success of the product via a reverse royalty to be paid until loss of exclusivity. To limit the duration of this reverse royalty by excluding Incyte’s U.S. patents from “Licensed Patent Rights” covering Jakafi in the U.S. would have made no commercial sense to Novartis in 2009 given the commercial realities of the structure of the deal, including the long duration until payback and with a lower share (split) of the risk adjusted value than proportional to its contributions. It also would have made no sense to limit the duration of the reverse royalty based on the identity of the patent owner given that “Regulatory Exclusivity” is not limited to who obtains the regulatory exclusivity.

Novartis' benefit, if any, of entering into the Agreement was in the back end of the duration of the parties' collaboration, meaning that Novartis might not get "above zero" for many years after the Agreement was signed. In fact, there was a much higher risk that Novartis would not get the bargained-for return on investment at all, as any number of things might have occurred before Jakafi/Jakavi was launched that could have frustrated the parties' ability to earn anything from the product (*e.g.*, lack of clinical trial success, lack of regulatory approval(s)). While ruxolitinib ended up being approved and was commercially successful both in the U.S., and outside the U.S., there was no certainty to this at the time the deal was being negotiated in 2009.

By way of example, obtaining regulatory approval in all countries outside the U.S. would have been a more complex undertaking for Novartis than getting regulatory approval in the U.S. would have been for Incyte, given that no steps had yet been undertaken in the ex-U.S. market before the Agreement was signed. Further, the regulatory and medical practices are more fragmented outside the U.S. than in the U.S., in that there are multiple regulatory agencies, and with different medical practices and standards, the likelihood of meeting the needs of all countries (*e.g.*, with clinical trial data) was reduced. These two points would have made the deal riskier for Novartis and would have made the value of the reverse royalty more important, because approval and thus sales in the U.S. were more likely than approval and sales outside the U.S. In my experience, and as is custom and practice in the industry, the complexity of getting approval outside the U.S. factors into the structure and financial terms of licensing agreements with ex-U.S. and U.S. territorial splits.

Novartis' Committee presentation calculations of NPV/eNPV are also informative. With a long payback time (discussed further below), and the normal risks of drug development, it is not reasonable to focus only on the nominal cash flows in assessing the attractiveness of the deal—*i.e.*, it is necessary to look at the risk and time-adjusted cash flows. Novartis used eNPV (risk adjusted NPV) calculations to see if the deal was fair and sensible to enter, as is customary in the industry. Overall, the eNPV balance between Novartis and Incyte was such that any reductions to the economics would threaten to kill the deal because it would no longer make financial sense for Novartis. A change in the duration of the reverse royalty, even if small in absolute dollars in the cash flow modeled at the time based on available forecasts in 2009, would push the deal further outside the range where Novartis expected to be fairly compensated on a risk and time basis.

In short, getting that back-end benefit would necessarily mean getting reverse royalties until loss of exclusivity in the U.S., irrespective of whether the patent(s) protecting the product from third party competition was owned by Incyte. This is true even though Novartis' reverse royalty rates only amount to a small fraction of Incyte's U.S. sales (2%-5% of net sales in the United States), whereas Incyte received (and still receives) a much greater share of Novartis' sales of Jakafi outside the United States (18% to 24%). As Todd MacLaughlan testified at his deposition "if you didn't have the royalty rate going out to the patent expiry date, there wouldn't be enough . . . to offset the amount of money going out of Novartis' treasury" and Novartis "wanted to feel compensated for the value they were bringing to the table[.]" Tr. 369:2-23.

In addition, I see no commercial rationale for interpreting "Licensed Patent Rights" in such a way that Novartis would have had to get a hypothetical patent in the United States at some point in the future, following execution of the Agreement, to continue to receive reverse royalties for

more than 10 years (and not be subject to a 50% reduction during that 10-year window). Given that Incyte already held the IP and patents associated with the JAK compound at the time the Agreement was signed, it would have made no sense for Novartis to enter into an agreement that limited the reverse royalty term to ten years *unless* it later got some sort of patent in the United States and licensed it to Incyte under the Agreement. This hypothetical scenario would not have enabled Novartis to have the NPV/eNPV value splits make financial sense for Novartis.

**C. Any suggestion that Novartis already achieved “payback” and thus has sufficiently obtained an appropriate return on its investment is inconsistent with commercial realities.**

Final Novartis management presentations included a calculation of the number years it would take for Novartis to achieve “payback.” Payback is an industry term for the point at which a party breaks even on its investment and begins to earn a profit. The final Committee presentations project that Novartis would not achieve payback with respect to the JAK compound until approximately 10 years after the deal was signed in the “base case” scenario. NOVARTISPROD000002813. Based on my experience, 10 years is a long payback period, especially for a deal struck at Phase III (where the JAK compound was at the time). LOE was assumed to be in 2025 and launch in Europe was expected in 2012 (NOVARTISPROD000002812), so there were only 13 years of ex-U.S. sales before potential generic entry was expected to erode the sales. This means Novartis expected very few years of high profit sales beyond the estimated year of break-even to make a profit on its investment in the deal. Put differently, Novartis was spending from 2009 onward, but only expecting to get a return on the deal after 2019 (notably, the year that Incyte unilaterally told Novartis it would be reducing royalties by 50%). If in 2009 Novartis understood that the reverse royalty was potentially to end in 2019, the reverse royalty would be making no contribution to the return after the breakeven year and the return on investment on the deal in the few years before generic entry would have been significantly riskier. To be clear, the Agreement was not and never intended to be a deal by which Novartis was just looking to “break even” or be “paid back” the amount of money it contributed to the development and commercialization efforts. The Agreement was not a loan to Incyte. Rather, the deal was that Novartis would assume the risk and make the significant contributions on the front end in anticipation that the product would be commercially successful (both in the U.S. and abroad) so that both Novartis and Incyte could reap financial benefits from that success. It is important to note that a company passes on other potential deals with upside potential when it commits funding and resources to a given transaction.

Given the payback period, it is my expectation, based on industry custom and practice and my own experience, that a company like Novartis would view both repayment streams as valuable components to the financial terms of the deal: (1) revenues earned from Novartis’ sales of ruxolitinib outside the U.S., and (2) the reverse royalty providing Novartis with a share of Incyte’s sales of ruxolitinib in the U.S. That is true irrespective of what the forecasted sales of ruxolitinib were at the time in 2009. Although back in 2009 Novartis projected that the reverse royalty repayment stream would be less in absolute dollars than the amount of money it expected to earn from ex-U.S. sales of ruxolitinib, that reverse royalty would have been an important revenue stream to Novartis in that there would be no associated expenses that would need to be subtracted from the reverse royalty payments and there was less regulatory uncertainty for royalties on U.S. sales than for the sales in the rest of the world. Given the lengthy payback period and the more

advanced state of regulatory interactions in the U.S. than ex-U.S., it is my expectation that Novartis would have considered it important to protect and maximize that reverse royalty stream.

**D. The ongoing and increasing commercial success of Jakafi in the U.S., as Incyte continues to maintain market exclusivity given the patent protections, further supports my opinion.**

It would not be commercially logical to limit the duration of the reverse royalty to ten years, with the last three years of reverse royalty payments reduced by 50%, while Incyte maintains its protected market position given its Orange Book-listed patents and continues to make billions of dollars a year on net product revenues. Incyte's annual 10-K filings of the last few years indicate that sales have only continued to rise exponentially since the myelofibrosis orphan drug designation's expiration in Q4 2018, when Incyte reported \$1,386,964,000 in Jakafi revenue:

<b>Incyte 10-K For Year</b>	<b>Reported Jakafi Revenue</b>	<b>Percent Increase From Prior Year</b>
2019	\$1,684,968,000	21.5%
2020	\$1,937,850,000	15.0%
2021	\$2,134,508,000	10.1%

Incyte has incurred no detrimental impact on its market position and so there is no commercially logical reason why it should not be required to pay Novartis its, at most, 5% share, given Novartis' various contributions over time to the commercialization of the drug.

**III. Both parties' financial modeling and valuation analyses with respect to the reverse royalty are consistent with an understanding that the reverse royalty would be paid for well more than ten years.**

In negotiating a collaboration and licensing agreement or any amendment thereto, it is standard practice for both sides to engage in financial modeling and valuation analyses to decide whether to accept a certain deal term, propose a counteroffer on a particular term, or walk away. Here, the parties' respective financial modeling and valuation analyses clearly reflect the incorporation and consideration of the reverse royalty, both with respect to rate and duration, at the term sheet stage and beyond, through to contract execution.


I have considered the testimony of two Incyte witnesses, Herve Hoppenot and Keith Mikkelsen, who testified that the final term sheet was supposedly unclear as to the duration of the reverse royalty and that Incyte's first draft of the contract allegedly sought to clarify that by making clear that it would be limited to ten years in the U.S. unless Novartis obtained another patent covering Jakafi in the U.S. that aided Incyte in its commercialization efforts. It is my opinion that this sequence of events does not make commercial sense, both because (1) the term sheet is clear and unambiguous on how to calculate the duration of any royalty term (including the reverse royalty) and (2) the duration of a royalty term is a financial deal term that would have been finalized at the term sheet stage, and had that point been attempted to be renegotiated by Incyte, that would be reflected as a discussion point in the documentary record and in the valuation analyses and financial modeling done by both sides. My review of the Goldman Sachs documents

supports that no such change to the duration of the reverse royalty was made (and the latest modeling had reverse royalties continuing for well more than 10 years after launch and until 2029). Relatedly, I have reviewed the report of Novartis' expert Larry Tedesco and agree with his conclusions as far as what the financial modeling performed on Incyte's behalf reflects as far as the duration of the reverse royalty.

Nothing in the Goldman Sachs modeling from 2009 reflects an assumption of a hypothetical Novartis patent in the future or scenario testing based on that contingency, either, which I would have expected to see as a matter of custom and practice if in fact "Licensed Patent Rights" was tied to the identity of the patent holder, as Incyte contends in this litigation.

### **CONCLUSION**

For all of the reasons summarized herein, it is my opinion that, in considering the relevant industry customs and practices, the Agreement between Novartis and Incyte as a whole, the commercial rationales underlying BD&L deals and this deal in particular, and the reasonable understanding of the parties at the time of contracting based on industry customs and practices as applied to the factual sequence of events, among other things, the duration of the reverse royalty to be paid by Incyte to Novartis is to continue pursuant to the agreed-upon reverse royalty rates, without any 50% reduction, until at least the loss of exclusivity (*i.e.*, the expiration of Incyte's patents covering the subject product in the United States). Given industry customs and practices and commercial rationality, it is my further opinion that, whatever Incyte may now maintain in this litigation, such an understanding of the Agreement is the most commercially reasonable and appropriate interpretation and application of clause (i) of Section 8.3(c) under the circumstances.

Signature:   
Linda M. Pullan, Ph.D.

Date: May 4, 2022



**EXHIBIT A:**  
**Documents Considered**

<b>Novartis Pharma AG v. Incyte Corporation</b>	
<b>Case No. 1:20-cv-00400</b>	
<b>Materials Considered by Linda Pullan</b>	
<b>BATES NUMBER / NAME OF DOCUMENT</b>	
<b>Court Filings</b>	
Novartis' Complaint	
Incyte's Memorandum of Law in Support of its Motion to Dismiss	
Novartis' Memorandum of Law in Opposition to Incyte's Motion to Dismiss	
Incyte's Reply Memorandum of Law in Further Support of its Motion to Dismiss	
Memorandum Opinion and Order on Incyte's Motion to Dismiss, dated Feb. 18, 2021	
Corrected Memorandum Opinion and Order on Incyte's Motion to Dismiss, dated Feb. 22, 2021	
Incyte's Answer	
<b>Collaboration Agreement and Amendments</b>	
NOVARTISPROD000031298-424	
NOVARTISPROD000031425	
NOVARTISPROD000031426	
NOVARTISPROD000031427-30	
NOVARTISPROD000031431-46	
NOVARTISPROD000031447-58	
<b>Deposition Transcripts and Exhibits</b>	
Transcript of the deposition of David Butera and Exhibits 1-16	
Transcript of the deposition of Jennifer Gallagher and Exhibits 101-116	
Transcript of the deposition of Brian Goldfus and Exhibits 201-231	
Transcript of the deposition of Blake Benner and Exhibits 1-16	
Transcript of the deposition of Kimberly Solomon and Exhibits 1-21	
Transcript of the deposition of Manuel Litchman and Exhibits 301-329	
Transcript of the deposition of Patricia Andrews and Exhibits 1-31	
Transcript of the deposition of MaryAnne McCarthy and Exhibits 1-19	
Transcript of the deposition of David Hastings and Exhibits 1-18	
Transcript of the deposition of Todd MacLaughlan and Exhibits 501-523	
Transcript of the deposition of Tom Gayer and Exhibits 1-18	
Transcript of the deposition of Nancy Griffin and Exhibits 601-619	
Transcript of the deposition of Steven Singer and Exhibits 1-22	
Transcript of the deposition of Paul Friedman and Exhibits 1-20	
Transcript of the deposition of Douglas Hager and Exhibits 801-820	
Transcript of the deposition of Herve Hoppenot and Exhibits 1-19	
Transcript of the deposition of Daniel Maravei and Exhibits 1-25	
Transcript of the deposition of Keith Mikkelsen and Exhibits 1-22	
Transcript of the deposition of Shelley Sun and Exhibits 701-706	
Transcript of the deposition of Teresa Jose and Exhibits 901-914	
Transcript of the deposition of Marshall Smith and Exhibits 1-17	
Transcript of the deposition of Paul Trower and Exhibits 1-24	
Transcript of the deposition of Laurent Chardonnet and Exhibits 1-4	
<b>Incyte Produced Documents</b>	
INCY000002917-99	
INCY000003000-175	

BATES NUMBER / NAME OF DOCUMENT	
INCY000025233-334	
INCY000119691-92	
INCY000123643-891	
INCY000124298-405	
INCY000124940-5218	
INCY000126419-6709	
INCY000150412-503	
INCY000150504-632	
INCY000150633-703	
INCY000150873-1012	
INCY000151619-808	
INCY000159264-366	
INCY000161738-874	
INCY000162847-905	
INCY000168480-81	
INCY000168482-95	
INCY000168496-518	
INCY000168519-29	
INCY000168530-31	
INCY000168532-33	
INCY000168534-38	
<b>Novartis Produced Documents</b>	
NOVARTISPROD000001349-1422	
NOVARTISPROD000001349-422	
NOVARTISPROD000001422	
NOVARTISPROD000001455-57	
NOVARTISPROD000001898-900	
NOVARTISPROD000002312-553	
NOVARTISPROD000002757-828	
NOVARTISPROD000002757-844	
NOVARTISPROD000002973-3220	
NOVARTISPROD000003469-719.0018	
NOVARTISPROD000003903-4172	
NOVARTISPROD000004993-96	
NOVARTISPROD000005248-569	
NOVARTISPROD000005580-808	
NOVARTISPROD000005943-74	
NOVARTISPROD000006916-19	
NOVARTISPROD000007459-82	
NOVARTISPROD000012731	
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NOVARTISPROD000013002-04	
NOVARTISPROD000013002-27	
NOVARTISPROD000013100-08	
NOVARTISPROD000013112-14	
NOVARTISPROD000013415-16	

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NOVARTISPROD000013733-34
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NOVARTISPROD000015407-15
NOVARTISPROD000016124-29
NOVARTISPROD000016163-87
NOVARTISPROD000016235-36
NOVARTISPROD000016249-50
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NOVARTISPROD000016930-53
NOVARTISPROD000017828-29
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NOVARTISPROD000029261-67
NOVARTISPROD000039324-33
NOVARTISPROD000041846-81
NOVARTISPROD000052149-68
NOVARTISPROD000058663-66
NOVARTISPROD000082302-12
NOVARTISPROD000082958-3145
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NOVARTISPROD000089644-45
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NOVARTISPROD000096377
NOVARTISPROD000097760-8088
NOVARTISPROD000098249-67
NOVARTISPROD000098308-25
NOVARTISPROD000100084-110
NOVARTISPROD000127227-500.0009
NOVARTISPROD000128240-42
NOVARTISPROD000128240-42
NOVARTISPROD000130297-302
NOVARTISPROD000137368-70
NOVARTISPROD000141147-85
NOVARTISPROD000141619-26
NOVARTISPROD000141757-59
NOVARTISPROD000141858-907
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NOVARTISPROD000142006-18
NOVARTISPROD000142209-25
NOVARTISPROD000142266-71

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NOVARTISPROD000142306-10
NOVARTISPROD000151372-538
NOVARTISPROD000151760-62
NOVARTISPROD000154913-22
NOVARTISPROD000157968-77
NOVARTISPROD000158328-37
NOVARTISPROD000164835-38
NOVARTISPROD000164839-40
NOVARTISPROD000165232-77
NOVARTISPROD000170451-64
NOVARTISPROD000173325-56
NOVARTISPROD000173325-56
NOVARTISPROD000181154
NOVARTISPROD000176016-206
NOVARTISPROD000176596-97
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NOVARTISPROD000184002-04
NOVARTISPROD000187771-76
NOVARTISPROD000189118-35
NOVARTISPROD000189253-59
NOVARTISPROD000189687-97
NOVARTISPROD000189845-48
NOVARTISPROD000202229-60
NOVARTISPROD000202304-26
NOVARTISPROD000211167-68
<b>Goldman Sachs Produced Documents</b>
GS0000001-02
GS0000019-21
GS0000063-68
GS0000069-72
GS00002239
GS0000365-68
GS0000367
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GS0000369-96
GS0000402-24
GS0000427-31
GS0000508-10

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GS0000511-12
GS00006461-67
GS0000801-11
GS0000840-61
GS0000868-69
GS0000880-82
GS0000894-95
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GS0000915-42
GS0000943-66
GS0001001-231
GS00010758
GS0001572-73
GS0001234-35
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GS0001593-602
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GS0002207-23
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GS0002242-52
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GS0002831-3018
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GS0006667
GS0006669
GS0006670-730
GS0006730
GS0006754-58
GS0010706-33
GS0010734-41
GS0010829-30
<b>Discovery Requests and Responses</b>
Novartis' Responses to Incyte's Second Set of Interrogatories, dated April 21, 2022
Novartis' Responses and Objections to Incyte's First Set of Interrogatories, dated March 28, 2022
Novartis' Responses and Objections to Incyte's Requests for Admission, dated March 15, 2022
Incyte's Responses and Objections to Novartis' Contention Interrogatories, March 30, 2022
Incyte's Responses and Objections to Novartis' First Set of Requests for Admissions, dated March 15, 2022
Incyte's Responses and Objections to Novartis' First Set of Interrogatories, dated June 1, 2021
<b>Publications</b>
DiMasi, J., "New Drug Innovation and Pharmaceutical Industry Structure: Trends in the Output of Pharmaceutical Firms," <i>Drug Information Journal</i> 34: 1169-94 (2000)
Nicholson, S., <i>et al.</i> , "Biotech-pharmaceutical alliances as a signal of asset and firm quality," <i>Journal of Business</i>
Paul, S.M., <i>et al.</i> , "How to improve R&D productivity: the pharmaceutical industry's grand challenge," <i>Nature Reviews Drug Discovery</i> 9: 203-214 (2010)

<b>BATES NUMBER / NAME OF DOCUMENT</b>	
Wouters, O.J., <i>et al.</i> , "Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018", <i>JAMA</i> 323(9): 844-853 (2020)	
<b>SEC Filings</b>	
Incyte Corp 10-K (FY 2008)	
Incyte Corp 10-K (FY 2009)	
Incyte Corp 10-K (FY 2010)	
Incyte Corp 10-K (FY 2011)	
Incyte Corp 10-K (FY 2012)	
Incyte Corp 10-K (FY 2013)	
Incyte Corp 10-K (FY 2014)	
Incyte Corp 10-K (FY 2015)	
Incyte Corp 10-KA (FY 2015) (3/15/2016)	
Incyte Corp 10-K (FY 2016)	
Incyte Corp 10-KA (FY 2016) (3/17/2017)	
Incyte Corp 10-KA (FY 2016) (6/30/2017)	
Incyte Corp 10-K (FY 2017)	
Incyte Corp 10-K (FY 2018)	
Incyte Corp 10-K (FY 2019)	
Incyte Corp 10-K (FY 2020)	
Incyte Corp 10-K (FY 2021)	
<b>Other Documents &amp; Sources</b>	
WH000003173-74	
AO_NOVA_00003981	
AO_NOVA_00004925	
<a href="https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&amp;Appl_No=202192&amp;Appl_type=N">https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&amp;Appl_No=202192&amp;Appl_type=N</a>	

**EXHIBIT B:**  
**CV of Linda M. Pullan, Ph.D.**

**Linda M. Pullan, Ph.D.**

**Pullan Consulting**

**www.pullanconsulting.com**

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work and cell 805-558-0361

[linda@pullanconsulting.com](mailto:linda@pullanconsulting.com)

Over 25 years of pharmaceutical and biotech experience. In-depth understanding and proven success in drug development, and evaluation, valuation and negotiation for strategic alliances and licensing deals.

**BUSINESS DEVELOPMENT EXPERIENCE**

**Pullan Consulting**

April 2006-present

Working for a variety of small and larger biotech as a business development consultant.

- Representing out-licensing efforts, coordinating out-licensing activities
- Seeking and evaluating opportunities for in-licensing
- Providing preliminary valuations, financial models for deals
- Negotiating and advising on negotiations on buy and sell side
  - Many signed deals (licenses as large as \$150MM upfront, options, and university licenses) for Preclinical to Phase III
  - Many term sheets always in progress
- Designing partnering presentations
- Advising on strategy and processes
- Leadership recognized:
  - Author of Pullan's Pieces with thousands of confirmed subscriptions
  - Taught negotiations courses, webinars on partnering, presentations on valuations, negotiations, diligence, including EBD Academy master course in negotiations
  - Led panels on oncology licensing, IO, ADCs, Bispecifics, and other science topics
  - Invited Speaker at BIO, BioEurope, BioEurope Spring, BioNetwork etc.
  - Served as interim CEO (Viriome, Inc.)
  - Served on Board of Directors (Aksivi, AUTM Foundation, Viriome, Paloma Pharmaceuticals, IRAD)

**Kosan Biosciences, Inc., Hayward, CA**

Oct 2004-March 2006

Vice President, Business Development

- Responsible for all business development activities, strategy, market analysis, financial models, messaging, relationship management and negotiations
- 9 negotiations initiated, 1 subsequently signed (**\$12.5MM** upfront)
- Chair committee for portfolio analysis, long-range planning
- Member of Operating Committee

**Amgen Inc., Thousand Oaks, CA**

Director, Oncology and Hematology Licensing

2000-2004

Associate Director, Oncology Licensing

1998-2000

- Created and led licensing team of 10 (including legal and finance) for Amgen's biggest therapeutic areas, oncology and hematology
- Generated 8 major deals and more than 10 others:
  - first clinical deal at Amgen (Ph 3, Praecis, **\$100MM** upfront)
  - Ph 2/3 cancer Ab (Immunomedics, **\$65MM**)
  - acquisition of kinase company Kinetix (**\$170MM**), now Amgen's Boston site
  - preclinical Ab (Vanderbilt) – milestones triggered since
  - targets and drug development (Tularik, **\$125MM**) – two milestones and acquisition since triggered
  - human Ab generation (Abgenix, Medarex, BioSite) – multiple milestones paid
  - drug delivery (Skye Pharma)

- companion diagnostics (Dako and Ventana)
- biomarkers (many)
- IP (many)
- Established review process, documents, diligence checklist now in use at Amgen
- Led identification, evaluation, valuation (market forecasts, deal terms and P&L models) and negotiations of technologies & products from targets to market
- Shaped strategy for therapeutic area, licensing, and research
  - Created monthly Therapeutic Area Leadership forum with heads of R, D, Sales and Marketing to drive strategy for all of oncology and hematology
  - Chosen to make presentations and contributions to Research reviews and strategy
  - Created, syndicated and communicated licensing strategy
- Sold value of Amgen for oncology partnering with capabilities pitches, negotiations, mass mailings, oncology licensing brochure, booths at congresses, and numerous speaking invitations

#### **Zeneca Pharmaceuticals, Wilmington, DE**

Collaborations (Licensing) Manager

1995-1998

Research Planning Analyst

1994-1995

- Led identification, evaluation and negotiations of academic and industry research collaborations
  - 4 Significant Deals
  - Established cost/value modeling for external alliances
  - Represented Zeneca at biopartnering conferences (E&Y, H&Q, Connect, Alex Brown)
- Defined neuroscience research, licensing, and hospital business strategies as part of teams
- Wrote Zeneca-wide international bioethics policy and guide
- Represented Zeneca on PhRMA Genomics Key Issues Team
- Continued to drive development strategy for clinical candidates for stroke, pain, other diseases
- Authored position papers on strategic options for senior R&D management

### **RESEARCH EXPERIENCE**

#### **ICI/Zeneca Pharmaceuticals and Monsanto/Searle**

Principal Pharmacologist

1992-1994

Project Leader

1992-1993

Senior Research Pharmacologist

1988-1992

Research Biochemist

1983-1988

- Contributed to promoting 3 drugs into the clinic; 1 now >\$1B sales
- Promoted to lead a team of biologists and chemists (~50 people)
  - Put a glycine antagonist into clinical development for cerebral ischemia (stroke) and pain
  - Contributed in vitro biology on Seroquel; now >\$1B plus antipsychotic on market
  - *In vitro* & *in vivo* biochemistry, receptor binding, second messengers, disease models, behavior
- Represented research team as member Development Strategy Team
- Chaired Zeneca U.S. Safety Committee

### **PUBLICATIONS**

- Produce monthly newsletter (Pullan's Pieces) on science and business for thousands of readers
- Webinars on Deal Prep, Partnering presentations, Valuation, Negotiations, What's Hot and What's Not in Oncology Licensing, Non-IO Oncology, ADCs, bispecifics, etc.
- Presented at many invited seminars and panels
- Authored 66 scientific literature publications
- Coauthor with VP of Research on paper on Zeneca's research strategy



### EDUCATION

**PhD**, in Biochemistry, minor in Chemistry, University of California, Riverside, 3.8 GPA

- Thesis research on enzyme isolation, kinetics, chemical modification, protein chemistry on the newly discovered carbonic anhydrase III and phosphoglucose isomerase

**BS** in Chemistry, University of Utah, 1978, Magna Cum Laude, 3.8 GPA

### HONORS

- Expert witness on licensing in litigation
- Reviewer for Australia's BTB and MRFF program grants
- Strategy review panel for Walter and Eliza Hall Institute
- American University Technology Managers Foundation board member (past)
- Taught master course in negotiation for EBD Academy, diligence course to pharma company
- Webinars and papers chosen by BIO to promote partnering
- Invited speaker for Keck Graduate Institute Advisory Board
- Reviewer for BioCurate incubator proposals
- Reviewer for USC start-up proposals
- Advisor for LARTA for small start-ups
- Lecturer for UCSD, UCSB on entrepreneurship, technology management
- Taught course in Norway for startups
- Taught basics of licensing course for Chinese pharmaceutical company
- Taught due diligence course for public biotech company
- Taught evaluations, valuations and negotiations for Asian company
- UCR College of Sciences Advisory Board
- Special Achievement awards at Amgen for Licensing
- Speaker on impact of new science on drug discovery for Zeneca's annual meeting, as Research Team Leader at SEROQUEL® launch meeting
- Special Achievement Award for coordinating R&D exhibits at Zeneca annual meeting
- Reviewer for Eur. J. Pharmacol.
- Two Zeneca Outstanding Achievement Awards
- Outstanding Teaching Assistant Award and Regents Fellowship from UC system
- Phi Beta Kappa, Phi Kappa Phi, ACS Analytical Chemistry Award

**DEAL SHEET****Strategic Alliances (>\$20MM upfront)**

- Consulting Client- Big Pharma, \$40M upfront, \$300M total for preclinical small molecule. Advice on terms and negotiations.
- Consulting Client – Biotech, \$40M, company acquisition. Advice on terms and negotiations.
- Consulting Client – Chinese pharma, \$220M total for Phase 3. Advice on termsheet and contract.
- Consulting Client – Big Pharma, \$27.5M upfront for biologic asset starting Phase 1, did outreach, led negotiations
- Consulting Client – Big Pharma, \$150M upfront for Phase 3 asset. Advice on terms and contract.
- Consulting Client – Big pharma, \$1B in milestones for 3 molecules. Led negotiations.
- Consulting Client – Big pharma, \$56M upfront, \$440M in milestones for 1 molecule, additional terms for other 2 molecules. Led negotiations for one of the biggest deals in China.
- Consulting Client – Big pharma, \$100MM upfront cash and equity, Phase 3, negotiations, advice on terms and final contract
- Consulting Client – Big Asian Pharma, \$25MM upfront, valuation, advice on negotiations (Phase 3)
- Consulting Client – Big pharma, \$25MM upfront, negotiations and advice (pseudo auction, pre-completion of Phase II)
- Consulting client – Big Pharma: \$30MM upfront, broad chemistry collaboration; advice and deal structure
- Tularik –Amgen: \$125MM, targets and drug development, led evaluation team, launched collaboration that led to acquisition
- Praecis – Amgen: \$100MM, Ph 3 GnRH antagonist, led evaluation team
- Immunomedics – Amgen: \$65MM, Ph 2/3 NHL Ab, led evaluation team and member of negotiation team
- Abgenix – Amgen: multi-antigen Ab creation, supervised evaluator and negotiator
- Medarex – Amgen: multi-antigen Ab creation, supervised evaluator and negotiator
- Kinetix acquisition by Amgen – \$170MM, kinases and structural biology, led evaluation and diligence

**Mid-Size Deals (>\$10M upfront)**

- Consulting Client – Big pharma, \$15M upfront, \$550M in milestones. Introduction and advice thru out negotiations.
- Consulting Client – Non-profit, negotiation advice (preclinical)
- Consulting Client – US Biotech, negotiations and advice (Phase II)
- Consulting Client – Regional Pharma, negotiations and advice (Phase II)
- Consulting Client – venture firm, sale of Phase I asset
- Consulting Client – US Biotech, negotiations and advice (Phase 1)
- Consulting Client – Mid-size pharma, option; led negotiations
- Consulting Client – Big pharma, discovery collaboration, on negotiation team
- Consulting Client – Major Pharma, advised negotiator (preclinical)
- Vanderbilt – Amgen: preclinical Ab, led negotiation
- Biosite – Amgen: multiple Abs, supervised evaluator and negotiator
- Incyte – Zeneca: genomics database, on negotiation team
- Pharmacopeia – Zeneca: combinatorial chemistry, on negotiation team
- U C Irvine – Zeneca: lead optimization ion channels, led evaluation and negotiations
- U College of London – Zeneca: small molecule lead, led renegotiations

**Smaller Deals**

- Consulting Client – Australian research institute, research collaboration, led negotiations
- Consulting Client – US Biotech, research collaboration, led negotiations
- Consulting Client – Diagnostics company, license, advice on negotiations
- Consulting Client – university, research collaboration, negotiated
- Consulting Client – EU biosimilars co, license, negotiated
- Consulting Client – US biotech, clinical trial collaboration, advice
- Consulting Client – UK biotech, Covid-19 deal, advice
- Consulting Client – US biotech, in-licensing bispecific, negotiated
- Consulting Client – US biotech, Global pharma pilot study, negotiated
- Consulting Client – UK biotech, CRUK clinical trial deal, advised
- Consulting Client – Chinese Ab generation, terms negotiation
- Consulting Client – US biotech, academic in-license, negotiated
- Consulting Client – European biotech, platform deal, advised on value and negotiations
- Consulting Client – China biotech, preclinical Ab, advised negotiator
- Consulting Client – China biotech, preclinical bispecific, advised negotiator
- Consulting Client – China biotech, preclinical vaccine, advised negotiator
- Consulting Client – US biotech, out-licensing Ab, advised negotiator
- Consulting Client – China company, in-licensing from biotech co, led negotiation
- Consulting Client – China company, ww rights for University asset, advised negotiator
- Consulting Client – computational chemistry collaboration, big pharma, advised negotiator
- Consulting Client – chemistry LO and license, \$500M milestones, global pharma, advised negotiator
- Consulting Client – small biotech, advised negotiator (preclinical)
- Consulting Client – small biotech, advised negotiator (preclinical)
- Consulting Client – University, advised negotiator (clinical)
- Consulting Client – University, advised negotiator (preclinical)
- Consulting Client – small biotech advised negotiator (preclinical)
- Consulting Client – Japanese pharma, participated in negotiations
- Consulting Client – global pharma, use patent, advised negotiations
- Consulting Client – University, negotiations
- Consulting Client – University, negotiations
- Consulting Client – Small biotech, JV, participated in negotiations
- Consulting Client – small biotech, territorial deal (preclinical), participated in negotiations
- Consulting Client – University (clinical), valuation, advice throughout negotiations
- Consulting Client – University (platform), led negotiations
- Consulting Client – Mid-sized pharma, led negotiations (preclinical)
- Consulting Client – Mid-sized pharma, advised negotiations (platform)
- Consulting Client – Global pharma, valuations, advised negotiator (preclinical)
- Consulting Client – Small biotech, valuations, advised negotiator (preclinical)
- Consulting Client – Global pharma, part of negotiations (preclinical)
- Consulting Client – Small biotech, led negotiations (preclinical)
- Consulting Client – Small biotech, led negotiations (preclinical)
- Consulting Client – University, led in-licensing negotiations (preclinical)
- Consulting Client – University, led in-licensing negotiations (preclinical)
- Consulting Client – University, led in-licensing negotiations (preclinical)

- Consulting Client – small biotech, led in-licensing negotiations (preclinical)
- Dako – Amgen: companion diagnostic development, supervised evaluator, led negotiations
- Ventana – Amgen: companion diagnostic development, supervised evaluator, led negotiations
- Skye Pharma – Amgen: drug delivery, led evaluation and negotiations
- Many biomarker deals – supervisory roles
- Many IP licenses – negotiator and supervisory roles, some as consultant

### **Webinars (incomplete)**

- What's hot and what's not in IO 2021? (organizer and moderator)
- What's hot and what's not in oncology licensing? (organizer and moderator)
- What's hot and what's not in antibody drug conjugates? (organizer and moderator)
- Adoptive Cell Therapy: The who, how and when. (organizer and moderator)
- Bispecific antibodies: are two really better than one? (organizer and moderator)
- Paradigm changing technologies in oncology (organizer and moderator)
- China investments and licensing deals (speaker)
- LES Pullan's Pieces III: A business development view of the immunology landscape. (speaker)
- LES Pullan's Pieces II: A business development view of the CNS landscape. (speaker)
- LES Pullan's Pieces I: A business development view of the oncology landscape. (speaker)
- Getting ready for a biopharma partnering deal (speaker)
- Nuts and bolts of due diligence in biopharma partnering (speaker)
- Winning strategies. How to create, grow and sustain a successful life science company (panelist).
- Anticipating and planning for deal dynamics (interviewed)
- Trends, challenges and opportunities in bispecific antibodies (moderator) BioEurope 2021.
- Targeting mRNA: The new frontier of tailored therapeutics (moderator) Demy Colton virtual salon.

### **Publications**

#### Whitepapers:

- Pullan LM. Successful biotech licensing negotiations
- Pullan, LM. Valuation of your early drug candidate. A no formulas tour of valuation.
- Pullan LM. Getting ready for a biopharma partnering deal.
- Pullan LM. A business development view of the oncology landscape.
- Pullan LM, et al., The nuts & bolts of due diligence in biopharma partnering.
- Pullan LM, et al., What's hot and what's not in oncology licensing in 2020?
- Pullan LM. How to win at the partnering game.
- Pullan LM, et al., What's hot and what's not in immune-oncology.
- Pullan LM, et al., What's the role of non-IO in an IO world.
- Pullan LM. Building a better partnering presentation.
- Pullan LM, et al., What's hot and what's not in antibody-drug conjugate (ADC) licensing.

### **Books and chapters**

- Pullan LM. "China licensing deals for biologics" in Advances in Biopharmaceutical Technology in China, 2nd ed., 2018, pp945-959. Bioplan.

### **Abstracts**

- Huang, C et al., A chemoproteomic platform for identifying small-molecule modulators of protein-protein interactions, discovering new cancer targets, and revealing previously unknown targets for well-known drugs. *Molecular Cancer Therapeutics* 2021, 20: 12S.

### **Newsletters**

- Email Newsletter Archives by Robly – Pullan Consulting